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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,328	12/12/2001	Amy Qi Han	PH-7203	4675

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/015,328	HAN ET AL.	
	Examiner	Art Unit	
	Rebecca L Anderson	1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8 is/are rejected.
- 7) ☒ Claim(s) 1,2,7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>27May 03</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1, 2, 7 and 8 are currently pending in the instant application, claims 14-22 were previously cancelled, claims 3-6 and 9-13 were cancelled in the amendment filed 2 July 2003 and claims 1, 2, 7 and 8 were amended in the amendment filed 2 July 2003. Claims 1, 2 and 7 are rejected, and claims 1, 2, 7 and 8 are objected.

#### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Specifically, applicants claims have two claim 7's. The claims have been renumbered as follows:

Misnumbered pending claim 7 (the second claim 7, which is found on page 31 of the claim amendments) has been renumbered as claim 8.

Misnumbered cancelled claims 8-21 have been renumbered as claims 9-22. Claims 1, 2, 7 and 8 are objected to for containing non-elected subject matter. Said claims presented drawn solely to the elected subject matter identified below and free of the following 35 USC 112 2<sup>nd</sup> paragraph rejections would appear allowable over the prior art of record.

***Election/Restrictions***

The subject matter of claims 1, 2, 7 and 8 other than that wherein:

The variables on the compound of formula I are:

**A<sup>1</sup>, A<sup>2</sup>, W, R<sup>1</sup>, R<sup>1a</sup>, R<sup>2</sup>, R<sup>3</sup>, p, R<sup>4</sup>, R<sup>4a</sup>, R<sup>4b</sup>, R<sup>4c</sup>, R<sup>4d</sup>, R<sup>9b</sup>, R<sup>9c</sup>, R<sup>9d</sup>, R<sup>9e</sup>, R<sup>11</sup>, R<sup>11b</sup>**

and **A<sup>3</sup>** are as found in amended claim 1,

**R<sup>9a</sup>** is selected from the group: H, -C(=O)R<sup>9b</sup>, -C(=O)OR<sup>9b</sup>, -C(=O)NHR<sup>9b</sup>, -C(=O)NHC(=O)R<sup>9b</sup>, C<sub>1</sub>-C<sub>6</sub> alkyl substituted with 0-3 R<sup>9c</sup>; C<sub>2</sub>-C<sub>6</sub> alkenyl substituted with 0-3 R<sup>9c</sup> and C<sub>2</sub>-C<sub>6</sub> alkynyl substituted with 0-3 R<sup>9c</sup> and

**OR<sup>26</sup>** and **OR<sup>27</sup>** taken together, form: e) a cyclic boronic ester where said cyclic boronic ester contains from 2-20 carbon atoms.

It is noted that this generic concept is equivalent to the generic concept as found in the office action mailed 19 May 2003 except for the value R<sup>9a</sup> which, with apologies from the examiner, did not encompass the elected compound of example 1 from Table 1 of the instant specification, the variable R<sup>9b</sup> which was excluded due to the incorrect value of R<sup>9a</sup> and the value of A<sup>3</sup> which has been changed to include both L and D configurations of valine. Therefore, the generic concept has been rewritten to correct the values for R<sup>9a</sup>, to add the value of R<sup>9b</sup> to correspond to applicants elected compound, to enlarge the value for the variable A<sup>3</sup> and to correspond to the variables as present in the amended claims.

The remaining subject matter of claims 1, 2, 7 and 8 that is not drawn to the above elected invention stands withdrawn under 37 CFR 1.142(b) as being for non elected subject matter. The remaining compounds which are not within the generic

concept, which are independent and distinct from the generic concept and do not have unity with the species elected and therefore are withdrawn by means of a restriction requirement within the claim are, for example, the compounds of formula (I) wherein:

R9a is  $-S(=O)_2R9b$ ,

OR26 and OR27 are independently selected from  $-OH$  and C1-C8 alkoxy and

R3 is 2-phenylquinolin-4-yl)methyl.

Some specific species of the withdrawn compounds are the species of

9H-fluoren-9-ylmethyl (1S)-1-(((5S)-5-(((1R)-1-  
[(3 $\alpha$ S, 4S, 6S, 7 $\alpha$ R)-hexahydro-3 $\alpha$ , 5, 5-trimethyl-4, 6-methano-1, 3, 2-  
benzodioxaborol-2-yl]propyl)amino)carbonyl)-2-oxo-3-[(2-phenyl-  
4-quinolinyl)methyl]imidazolidinyl)carbonyl)-2-  
methylpropylcarbamate;

which contains

a quinolinyl ring, a heterocycle classified in class 546 subclass 134(+) etc.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups which differ from those of the elected invention such as hydroxy and alkoxy (instead of a cyclic boronic ester class 558 subclass 286(+)) and quinolinyl, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 568 subclass 700(+) (hydroxy) class 546 subclasses 134(+) (quinolinyl), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non elected

subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

Therefore, Applicants' traversal of the restriction requirement has been considered but is not found persuasive. Applicants argue that if the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, then the examiner must examine all of the members of the Markush group. The above discussion of the withdrawn compounds responds to the argument that the Markush groups are sufficiently few in number or so closely related and in regards to the search and examination, the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Applicants' claims involve more than one independent or distinct invention. Under 35 U.S.C. 121, the claims may be restricted and the examination limited to a restricted invention. Accordingly, restriction as has been presented in this application is proper. The requirement to restrict is repeated and proper.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 7 are rejected under 35 USC 2<sup>nd</sup> paragraph because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "C<sub>3</sub>-C<sub>10</sub> carbocycle" on page 8, 9, and page 12 (2 instances) and the claim also recites "C<sub>3</sub>-C<sub>7</sub> cycloalkyl" and "aryl" which are the narrower statements of the range/limitation as can be seen by the instant page 63 of the

specification which states that carbocycle may be saturated, partially unsaturated or aromatic with examples such as cyclopropyl and phenyl. It is suggested that claim 1 be amended to include only the phrase containing "carbocycle" since this encompasses cycloalkyl and aryl.

Claim 1 is rejected under 35 USC 2<sup>nd</sup> paragraph because claim 1 recites the limitation for the values for the variable R<sup>11a</sup> in the compound of formula (I). There is insufficient antecedent basis for this limitation in the claim. There is no variable R<sup>11a</sup> found on the compound of formula (I). It appears that applicant mistakenly left this variable in the claim when amending the claim to include only elected subject matter. It is suggested that on page 14 of the amended claims "and R<sup>11a</sup> are, at each occurrence, independently" should be deleted from the claim and replaced with --is--.

Claims 2 and 7 are rejected under 35 USC 2<sup>nd</sup> paragraph because claim 2 recites the limitation for the value of the variable R3 as (2-phenylquinolin-4-yl)methyl in the compound of the formula (I) as found in claim 1 and claim 7 recites the compound

9H-fluoren-9-ylmethyl (1S)-1-(((5S)-5-(((1R)-1-  
((3aS,4S,6S,7aR)-hexahydro-3a,5,5-trimethyl-4,6-methano-1,3,2-  
benzodioxaborol-2-yl)propyl)amino)carbonyl)-2-oxo-3-[(2-phenyl-  
4-quinolinyl)methyl]imidazolidinyl)carbonyl)-2-  
methylpropylcarbamate;

There is insufficient antecedent basis for these limitation in claim 1. In the definition of the variable R3 (see apge 8 of the amended claims) in claim 1 there is no value that includes a heterocycle which is found in (2-phenylquinolin-4-yl)methyl. It is suggested that on page 20 of the amended claims, (2-phenylquinolin-4-yl)methyl should be deleted



from claim 2, and on page 29, the above mentioned compound should be deleted from claim 7.

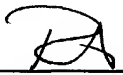
### Conclusion

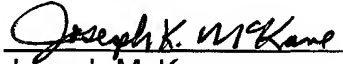
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

  
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